

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Examiner: Michener, Jennifer Kolb

Pacetti et al.

Serial No.: 10/040,538

Art Unit: 1762

Filed: 12/28/01

Title: A System and Method for Coating Implantable Devices

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration under 37 CFR § 1.132

I, Daniel Castro, declare the following:

1. I graduated from Massachusetts Institute of Technology in 1985 earning a BS degree in Chemical Engineering, with an emphasis on polymer science.
2. I have over 20 years of experience in the medical device and polymer fields, including experience in process and product development, coronary stent processing, polymer processing, coatings applications and drug eluting stent manufacturing operations.
3. I am currently employed by BioVascular Solutions, affiliated with Abbott Corporation, as a Manager, Process Manufacturing Engineering and Operations. (Prior to Abbott Corporation, BioVascular Solutions was an arm of Guidant Corporation.)

4. BioVascular Solutions is involved with the research, development and production of fully absorbable stents with a drug delivery coating.
5. I was employed by Guidant Corporation, a leading innovator of medical device products, as a Manager, Process Engineering Development from April 2001 to August 2004.
6. In my position as Manager, I have supervised engineers and group leaders in development and pilot programs; coordinated process transfers to larger scale production; specified requirements for clean room facilities; evaluated new process and material technologies for new products; and attended to process and product performance issues.
7. From January 2000 to April 2001 I was a Group Leader at Guidant Corporation.
8. In my position as Group Leader, I have supervised engineers and technicians in development of medical device programs; specified, evaluated, and procured equipment and fixturing for medical device programs; participated in strategic planning of product development projects; devised strategies for scale-up and transfer of new processes; evaluate new processes and material technologies for new products; and participated in troubleshooting process and product performance issues.
9. I was a Senior Manufacturing Engineer at Guidant Corporation from May 1998 to January 2000.
10. In my position as Senior Manufacturing Engineer, I proposed procedure and material modifications for process improvements; supported coronary stent manufacturing operations;

mapped process development strategy for future generation stents; initiated process development efforts for drug eluting stent program; and directed a cross-functional team to evaluate process and material alternatives.

11. I was employed as a Project Manager by Boston Scientific Corporation's Vascular Division from January 1994 to May 1998.

12. I was employed as a Process Engineer by Meadox Medicals from January 1991 to December 1993.

13. In my position as Process Engineer at Meadox Medicals, I developed and optimized processes for manufacture of zero preclot arterial prostheses; designed setups for medical device scale simulation of production operations; developed laboratory scale procedures into production scale processes; proposed and implemented changes of production procedures and characterization methods to improve medical device product quality; designed apparatus for manufacture of new products; and planned and performed process and product validations.

14. I was employed by Kingston Technologies as a Project Engineer from September 1988 to December 1990.

15. In my position as Project Engineer at Kingston Technologies, I extruded a novel hydrogel for biomedical tubing and coating applications; developed concepts, manufacturing and testing methods of new biomedical products; characterized plasticized extrudable hydrogel using NMR and melt rheology; directed the production and quality control of extrudable hydrogel;

standardized medical tubing production from compounding through finishing; and improved extrusion yields from 20% to >80%.

16. I was employed by Energia Inc. as a Research Engineer from November 1987 to September 1988.

17. In my position as a Research Engineer, I designed prototype and experimental apparatus for research and performed photochemical studies using lasers and lamps.

18. I am the first named inventor of U.S. Patent No. 6,395,326 assigned to Advanced Cardiovascular Systems Inc., which was a subsidiary of Guidant Corporation.

19. U.S. Patent No. 6,395,326 is now owned by Abbott Corporation.

20. I have read and understand the content of U.S. Patent No. 6,395,326.

21. I have read and understand the contents of Application Serial No. 10/040,538 assigned to Advanced Cardiovascular Systems Inc., now owned by Abbott Corporation.

22. I submit that U.S. Patent No. 6,395,326 does not teach "directing a gas, from a gas dispenser positioned at a distance from the coating dispenser, onto the implantable medical device, wherein if the solvent has a vapor pressure greater than 17.54 Torr at ambient temperature the temperature of the gas is adjusted to decrease the evaporation rate of the solvent, and if the solvent has a vapor pressure of less than 17.54 Torr at ambient temperature the temperature of

the gas is adjusted to increase the evaporation rate of the solvent,” as recited by claim 1 of Application Serial No. 10/040,538.

23. I submit that U.S. Patent No. 6,395,326 does not teach “blowing a gas, from a gas blower positioned at a distance from the coating dispenser, directly onto the implantable medical device to either increase or decrease the evaporation rate of the solvent from the composition on the implantable medical device, wherein if the solvent is non-volatile the temperature of the gas is adjusted to increase the evaporation rate of the solvent, and if the solvent is volatile the temperature of the gas is adjusted to decrease the evaporation rate of the solvent,” as recited by claim 23 of Application Serial No. 10/040,538.

24. I submit that U.S. Patent No. 6,395,326 does not teach “blowing a gas from a blower onto the stent to either increase or decrease the evaporation rate of the solvent from the coating substance on the stent based on the volatile properties of the solvent; and rotating the stent supported by the support assembly about a longitudinal axis of the stent,” as recited by claim 54 Application Serial No. 10/040,538.

25. I believe that U.S. Patent No. 6,395,326 fails to teach what is recited in the independent claims of the above-identified application.

26. I further declare that all statements made herein of our own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed on _____

Dan Castro